

TABLE 37

Summary of Pharmacokinetic Parameters of Test product (T) of Estrone Sulfate - Baseline adjusted (N = 24)					
Pharmaco-kinetic Parameter	Arithmetic Mean \pm Standard Deviation	Coefficient of Variation	Median	Minimum	Maximum
C_{max} (ng/mL)	13.9042 \pm 7.0402	50.6339	11.1500	1.3000	39.0000
AUC ₀₋₂₄ (ng \cdot hr/mL)	97.9953 \pm 80.8861	82.5408	76.2750	5.1025	338.0000
t_{max} (hr)	6.33 \pm 4.56	71.93	4.00	4.00	24.00

TABLE 38

Summary of Pharmacokinetic Parameters of Reference product (R) of Estrone Sulfate - Baseline adjusted (N = 24)					
Pharmaco-kinetic Parameter	Arithmetic Mean \pm Standard Deviation	Coefficient of Variation	Median	Minimum	Maximum
C_{max} (ng/mL)	19.2542 \pm 11.3633	59.0173	15.2000	7.0000	53.7000
AUC ₀₋₂₄ (ng \cdot hr/mL)	177.6208 \pm 166.2408	93.5931	124.0000	20.0000	683.0500
t_{max} (hr)	10.33 \pm	54.05	10.00	2.00	24.00

TABLE 39

Geometric Mean of Test Product (T) and Reference product (R) of Estrone Sulfate - Baseline adjusted (N = 24)			
Pharmacokinetic Parameter	Geometric Mean		
	Test Product (T)	Reference Product (R)	
C_{max} (ng/mL)	12.1579	16.8587	
AUC ₀₋₂₄ (ng \cdot hr/mL)	66.5996	121.5597	
t_{max} (hr)	5.49	8.83	

TABLE 40

Statistical Results of Test product (T) versus Reference product (R) for Estrone Sulfate - Baseline adjusted (N = 24)					
Pharmacokinetic Parameter	Geometric Least Square Mean				
	Test Product (T)	Reference Product (R)	Intra Subject CV %	T/R Ratio %	90% Confidence Interval
C_{max} (ng/mL)	12.3350	16.5470	48.02	74.55*	59.43-93.51
AUC ₀₋₂₄ (ng \cdot hr/mL)	68.5260	118.4170	73.87	57.87*	41.68-80.35

*Comparison was detected as statistically significant by ANOVA ($\alpha = 0.05$).

While the pharmaceutical compositions and methods have been described in terms of what are presently considered to be practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar embodiments. This disclosure includes any and all embodiments of the following claims.

The invention claimed is:

1. A pessary comprising about 25 μ g of 17 β -estradiol in a solubilizing agent comprising a medium chain oil, wherein after a single administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of 17 β -estradiol of about 19 pg*hr/ml to about 29 pg*hr/ml; and

2) a corrected geometric mean area under the curve (AUC)₀₋₂₄ of 17 β -estradiol of about 75 pg*hr/ml to about 112 pg*hr/ml,

wherein 17 β -estradiol is the only active hormone in the pessary.

2. The pessary of claim 1, wherein administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of estrone of about 9 pg*hr/ml to about 14 pg*hr/ml; and

2) a corrected geometric mean area under the curve (AUC)₀₋₂₄ of estrone of about 43 pg*hr/ml to about 65 pg*hr/ml.

3. The pessary of claim 1, wherein administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of estrone sulfate of about 416 pg*hr/ml to about 613 pg*hr/ml; and

2) a corrected geometric mean area under the curve (AUC)₀₋₂₄ of estrone sulfate of about 3598 pg*hr/ml to about 5291 pg*hr/ml.

4. A pessary comprising about 10 μ g of 17 β -estradiol in a solubilizing agent comprising a medium chain oil, wherein after a single administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of 17 β -estradiol of about 12 pg*hr/ml to about 18 pg*hr/ml; and

2) a corrected geometric mean area under the curve (AUC)₀₋₂₄ of 17 β -estradiol of about 42 pg*hr/ml to about 63 pg*hr/ml,

wherein 17 β -estradiol is the only active hormone in the pessary.

5. The pessary of claim 4, wherein the pessary further provides a corrected geometric mean time to peak plasma concentration (T_{max}) of 17 β -estradiol of about 1 hrs to about 3 hrs.

6. The pessary of claim 4, wherein administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of estrone of about 4 pg*hr/ml to about 7 pg*hr/ml; and

2) a corrected geometric mean area under the curve (AUC)₀₋₂₄ of estrone of about 20 pg*hr/ml to about 31 pg*hr/ml.

7. The pessary of claim 6, wherein the pessary further provides a corrected geometric mean time to peak plasma concentration (T_{max}) of estrone of about 4 hrs to about 8 hrs.

8. The pessary of claim 4, wherein administration of the pessary to a patient provides, in a plasma sample from the patient:

1) a corrected geometric mean peak plasma concentration (C_{max}) of estrone sulfate of about 10 pg*hr/ml to about 16 pg*hr/ml; and